K103801

MAY 2 0 2011

EMIT Corporation 510(k) Notification
HypothermX® HX100 Intravenous Fluid and Blood Warmer

510(k) SUMMARY

EMIT Corporation HypothermX®

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, section 807.92.

Sponsor's Name and Address: EMIT Corporation
17225 El Camino Real, Suite 350
Houston, Texas 77058
Contact Person: Darla J. Elkin
Elkin RC, LLC
42 North Chantsong Circle
The Woodlands, TX 77382
Telephone: (281) 450-8163
Facsimile: (281) 298-7277

Device Trade Name: HypothermX® HX100 Intravenous Fluid and Blood Warmer

Product Code: LGZ

Classification: Unclassified

Common Name: Fluid and Blood Warmer

Predicate Devices: eFlow™ Model 100 IV Fluid Warmer (K060537)
Thermal Angel™ Blood/Fluid Warmer Model 200
(K012031)

Device Description:

The HypothermX® Intravenous Fluid and Blood Warmer consists of a single unit that is placed between a standard IV infusion set and a standard IV extension set. HypothermX® is designed to warm blood, blood products and intravenous fluids at flow rates of up to and including 50-200 ml/min. HypothermX® will deliver temperatures of 38°C±3°C.

HypothermX's® fluid path is sterile and the entire warming unit is disposable after use. HypothermX® is battery operated. Blood, blood products and intravenous fluids travel through the sterile tubing and are heated by flameless catalytic combustion. The temperature of the device is accurately controlled by the device's electronics.

Intended Use:

The HypothermX® Intravenous Fluid and Blood Warmer is intended to warm blood, blood products and intravenous fluids prior to administration. The HypoThermX® is

Comparison of the Technological Characteristics of the New Device and Predicate Devices:

Features	HypothermX® Intravenous Fluid and Blood Warmer	Thermal Angel	eFlow Model 100
K#	Not yet assigned	K012031	K060537
Heating Method	Stainless steel tube heated by fuel (flameless catalytic combustion)	Heating blanket covering stainless steel tubing; heated by electrical resistance	Electrical Resistance
Temperature Control	Thermistors	Thermistors	Temperature Sensors
Alarm	Audio/Visual LED Indicators	Visual, LED Indicators	Audio/Visual LED Indicators
Alarm Conditions	Illumination: Blue (<35°C) Yellow (42-46°C) Red (>46°C). Audible alarm: Every 10-20 seconds (42-46°C) Every 1-2 seconds (>46°C). Safety ITCO switch turns off @ 50°C.	Illumination: Red fading to dim or no light = no power Green fading to dim or no light = decrease in heat. Safety switch turns off @47°C	Illumination: Blue Flashing (<33°C) Blue (33-34°C) Yellow (43-44°C) Yellow/Red Flashing (≥45°C) ITCO switch turns off at 50°C
Electronics	Microprocessor controlled	Microprocessor controlled	Microprocessor controlled
Power Source	Lithium Battery	Rechargeable Battery	115 or 230V AC; 12-30 V DC Battery
Flow	50-200 ml/minute	up to and including 200 ml/min	1-200ml/min
Optimum Infusion Temp.	38±3°C	38±3°C	35-42°C
Usage	Disposable	Disposable	Reusable device with disposable set

Discussion of Nonclinical Studies and Clinical Tests

Results of studies conducted on the sterilized fluid pathway demonstrate the materials to be biocompatible for its intended use. In addition, performance data demonstrate the temperature accuracy of the device at different flow rates. Laboratory evaluations have been conducted to evaluate the hemolytic effect of the HypothermX® during flow, stop flow, and high flow rates.

Rationale for Substantial Equivalence

The HypothermX® shares the same indication for use and the same or similar device operation and overall technical and functional capabilities and therefore is substantially equivalent to the predicate device. Any differences between the HypothermX® and the equivalent device have no significant influence on safety or effectiveness of the HypothermX® product.

Conclusion

The HypothermX® was found to be substantially equivalent to the predicate device as it shares the same intended use and the same or similar technological characteristics and thus is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 2 0 2011

EMIT Corporation
C/O Ms. Darla J. Elkin
President
Elkin Regulatory Consulting, LLC
42 North Chantsong Circle
Woodlands, Texas 77382

Re: K103801
Trade/Device Name: HypothermX® HX100 Intravenous Fluid and Blood Warmer
Regulation Number: Unclassified
Regulation Name: Blood and Plasma Warming Device
Regulatory Class: Unclassified
Products Code: LGZ
Dated: May 12, 2011
Received: May 13, 2011

Dear Ms. Elkin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103801

Device Name: HypothermX® HX100 Intravenous Fluid Warmer

Indications for Use:

The HypothermX® is intended to warm blood, blood products and intravenous solutions prior to administration. The HypothermX® is intended to be used by healthcare professionals in clinical and field environments.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5/20/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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